Quality Assurance for HIV testing

Key considerations and way forward in the context of Universal Health Coverage and Africa Health Security

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INTEREST 2019
Accra, Ghana
A better understanding of

- Quality Assurance (QA) within the larger aspects of Quality Management Systems (QMS)
- The link between QA and the achieving the goals of the 90-90-90, Universal Health Coverage and Global Health Security,
- The challenges and lessons learnt in QA _using external Quality Assessment (EQA)as a case
- Policy implications when advancing QA
Back to basics
Laboratory testing in the management of HIV

Screening
- HIV rapid tests
- Screening for OIs

Risk stratification
- CD4 count

Diagnosis
- HIV confirmatory tests
- Early Infant Diagnostic (EID)

Treatment selection
- HIV drug resistance testing
- HIV viral load

Monitoring
- HIV viral load
- CD4 count

Laboratory errors/malpractice
- Unrecognized HIV infections
- Unrecognized severity
- Unnecessary, delayed or inadequate treatment
- Continuous transmission of HIV
- Unfavorable clinical outcomes
- Additional direct and indirect costs
- Mistrust of laboratory tests

90-90-90
Some useful definitions (1)

**Quality Assurance (QA)**

- for ensuring quality in the processes of testing
- QA is a prevention tool and verifies the process of testing (staff competency, reagent, equipment results return, SOPs)

**Quality Control (QC)**

- for ensuring the quality of test results
- QC is a corrective tool and verifies the test result

Set of activities
Some useful definitions (2)

**Quality management system (QMS)**

- formalized *system* that documents processes, procedures, and responsibilities for achieving quality (ISO 15189)
Quality Control

Quality management systems

Systems for Continuous Quality Improvement towards accreditation are created and maintained (including audits)

Ex: Internal quality controls, equipment maintenance

Quality System

Leadership, responsibilities, organization are in place, and activities documented and tracked

Ex: Quality manual

Laboratory vision and mission, Internal audits

Quality Assurance

Measures to prevent errors and ensure quality are in place

Ex: External quality assessment

Ex: Internal quality controls, equipment maintenance

Quality Control

Control that testing is correct and safe

Ex: SLIPTA audit (benchmark to assess progress from 0 - 5 towards ISO15189)

SLMTA programs (how-to)
All diagnostics should be quality-assured everywhere and for everyone

- Appropriate identification of diseases
- Appropriate treatment
- Effective disease surveillance linked to clinical care

Universal Health Coverage

Effective prevention and public health action for Health Security in Africa
Q A Guidance for HIV testing over the years

PEPFAR/CDC
CHAI
EGPAF
UNITAID
WHO
ASLM
ICAP
USAID
LSHTM
Solthis
UNICEF
USAID

2011 2014 2015 2017 2018 2018
QUALITY ASSURANCE identifies what does not work
Within the quality assurance cycle, External Quality Assessment (EQA) is a minimum requirement for medical laboratories conducting HIV testing.
What is External Quality Assessment?

- EQA is here defined as a system for objectively checking the laboratory’s performance using an external agency or facility.

- It compares the performance of the laboratory assessed to a peer group of laboratories or to the performance of a reference laboratory.

- Identifies areas for improvement

- Part of accreditation requirements
Methods for EQA

Panel testing
Proficiency testing

Blind re-testing

Onsite evaluation

HIV – related PT schemes
- CD4 flow cytometry
- HIV serology
- HIV EID
- HIV viral load
- HIV DR testing
A typical EQA program

Organizing laboratory

- Prepare samples for the PT panel
- Analyze results
- Prepare report

Participating laboratory

- Examine Samples
- Report Results
- Identify gaps and take corrective actions

5 samples 2 - 6 times a year
Score of laboratory PASS/FAIL

Performance of all participating laboratories across the last 3 surveys

Comparison of Laboratory A and the rest of the participants

Benefits of EQA

- Provide early warning for systematic problems
- Increase confidence in the quality of a laboratory’s performance
- Serves as a quality indicator for stakeholders at various levels
- Quality evaluation and improvement of the testing process
- Demonstrate employee competency
- To monitor trends in results
- Contribute to post market surveillance of in vitro diagnostics
Key considerations when implementing EQA for HIV testing

**Increasing number of facilities to enroll**
- Tests and treat
- Scale up of VL and EID

**Evolving technology**
- Increasing automation. Less errors?
- Multiplicity of platforms and assays

**Evolving public health needs**: Recency assay (Y/N to quantitative response )

**Testing moving closer to the community**
- Point-of-care instruments
- Non-trained staff are conducting the tests
- Instruments are placed in remote areas
Lessons Learned

From PEPFAR
150,000 people living with HIV/AIDS

Screening algorithm
- based on serial testing of Determine HIV1/2 and Unigold HIV1-2
- All positive samples are retested

Survey in 2012 → 72% of surveyed sites with discrepant HIV RT results among pregnant women
Lessons learnt

- 163% increased participation between 2006 (from 70 to 160 labs).
- Good performance: average score >90%

- But EQA results did not reflect the performance of the testing sites
  - 53% of PT testing was done by the most experienced lab technician
  - HIV Testing Sites in the community were not participating

- Need to ensure that PT panel are treated like any routine sample
- Find ways to deliver EQA to HTS in the community
PT package

- 1 sheet of PT Panel (duplicate set of 5 DBS)
- 1 sheet of Positive Control (10 DBS)
- 1 sheet of Negative Control (10 DBS)
- Instructions and Process checklist form
Lessons learnt

Quality performance increases over time

- From 11 to 41 countries
- 1550 panels distributed

The higher the number of EID facilities in a country, the lower the score

10% of the laboratories do not achieve the 30 day turnaround time (TAT) for the return of results
Reasons for not participating or not meeting results TAT for EQA viral load

- No reagents
- Expired kits
- Instrument in need of repair
- Long delay in clearing customs
- Staff is reluctant to use reagent for EQA instead of patient testing
EQA in the context of the stepwise Process for Improving quality of HIV related Point-of-care testing (SPI-POCT) in Cameroon

SPI-POCT package includes guidance on:

- Integration of POCT service for Patient Care
  - Test the Right Patient
  - Test at the Right Time
  - Results used to support Patient Care
- Competency of testers (not only testing sites)
- Quality: Specimen, (not only) Testing, & Results
- Safe and Efficient POCT Environment
- Monitoring of Quality (including EQA)

- More effective building of quality systems
- But only 14 of 50 (facilities offering EID are supported through PEPFAR)
Summary of the remaining gaps in QA and EQA

- **Coverage**: QA and EQA should concern **ALL** laboratories and **ALL** HIV tests.

- **Relevance** of providing isolated QA components in the context where Health Systems supporting IHR and Health Security in Africa are needed.

  → EQA and QA to be delivered in larger national quality approach addressing system issues (workforce, sample transport, supply chain, accreditation).

- **Sustainability**: what will happen when international funding stops?
Some recommendations to advance QA for HIV testing
Increase capacity to produce EQA

Build capacity in more centers of excellence to support regional EQA PT programmes

- Produce/procure and distribute EQA PT
- Oversee logistic and management of the EQA program
- Serve as biobanking facilities for other EQA schemes of WHO-AFRO
Increasing contribution of local EQA providers under PEPFAR funding

EID PT Program

VL PT Program
Technology

- **Dried tubes**
  - Transported at room temperature
  - Inexpensive
  - HIV-1 RNA Viral Load testing [polymerase chain reaction (PCR) based assays]

- **Blood stabilizers**
  - Reduce the need for cold chain

- **Use ePT tool to report results**
  - Shortens the TAT of results

Workforce

**Train new cadre of workers** to facilitate EQA at community level
e.g. **Q-Corps** as community-based champions to promote the accomplishment of the QA cycle (SPI-POCT)

Finance

- Provide guidance to run EQA as a business (e.g. **NHLS**)
- Provide opportunities for the manufacturer /insurance companies to contribute to cost of maintaining QMS (AFCAD)
3 Support the expansion of national policy incorporating quality requirements

Bring QMS programs to the next level

- Country owned (e.g. franchise SLIPTA at regional or at country level - Ethiopia)
- Propose to use EQA requirement for the compulsory licensing of all public and private laboratories
- Revise national policies to include Quality requirement as a regulation

- Ensure that domestic funding is set aside for QMS
- Incentivize laboratories to take part in quality activities
SLIPTA stars recognition through a voluntary approach

Compulsory licensing and relicensing based on certification
Some thoughts on the achievement of SLIPTA to date

20 of 52 countries of the WHO-AFRO region are engaged

<table>
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<th>Countries</th>
<th># of laboratories engaged in SLIPTA</th>
<th>Estimate of the total number of laboratories in the public sector</th>
<th>% coverage</th>
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The overall distribution of SLIPTA score does not significantly change as the WHO-AFRO/ASLM SLIPTA programme matures and investment in QMS are made. Because policy enablers are not in place!
Uprising leadership for SLIPTA implementation at regional level

- ASLM and WAHO collaboration
- Strengthening the Regional Reference Laboratories in West Africa
- 27 laboratory professionals trained on SLIPTA auditing in November 2018

- ASLM and ECSA-HC collaboration in auditing and training
- Training of trainers to support the network in ECSA region and beyond
- 19 laboratory professionals trained in February 2019
Thank you

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